IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	
Hirsh, J. *et al.*	Group Art Unit: 1616
Application No: 10/565,346	Examiner: M. Haghighatian
Filed: January 20, 2006	Docket No.: **CPX-015.01**
Title: *Topical Aerosol Foams*	

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In response to the Advisory Action in the above-identified patent application, which was mailed November 7, 2008, Applicants respectfully submit this paper.

Claim Rejections under 35 USC § 103(a)

The Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness with respect to the rejected claims. According to MPEP § 2143, in order to establish a *prima facie* case of obviousness, a number of criteria must be met. For example, all of the limitations of a rejected claim must be taught or suggested in the prior art reference (or references when combined) relied upon by the Examiner; or they must be among the variations that would have been "obvious to try" to one of ordinary skill in the relevant art in light of the cited reference(s). Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria. Specifically, the Examiner has not presented a combination of references that qualify as prior art, which teach or render "obvious to try" the use of hydrofluoroalkanes (HFAs) as a propellant in the claimed formulations.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 103(a).

US 2006/0140984 in view of US 5,143,717

The Examiner contends that claims 1 and 3-13 are obvious over US 2006/0140984 in view of 5,143,717. The Applicants respectfully traverse.

As noted in the Applicants' Response to the Final Office Action (see Response, October 10, 2008, pages 4-5), US 2006/0140984 is based on a PCT application published as WO 2004/037225. This PCT application claims priority to two earlier-filed applications. Most importantly, a discussion of hydrofluoroalkanes as possible propellants in the systems described in this family of applications *does not appear in either priority document*. Indeed, this class of propellants is first mentioned in WO 2004/037225, filed October 24, 2003. Critically, the effective filing date (October 24, 2003) of the disclosure regarding hydrofluoroalkane propellants is AFTER the filing date of the earliest-filed provisional application to which the instant application properly claims priority (October 3, 2003). Therefore, US 2006/0140984 does not

qualify as prior art under 35 USC § 102(e) teaching "hydrofluoroalkane propellants" against any of the rejected claims.

Further, US 5,143,717 does not teach hydrofluoroalkane propellants. In other words, combining the teachings of US 2006/0140984 and US 5,143,717 does not resolve the shortcomings of US 2006/0140984 vis-à-vis the requirement for a hydrofluoroalkane propellant in the rejected claims.

US 2006/0233721 in view of US 6,075,056

The Examiner contends that claims 1 and 3-13 are obvious over US 2006/0233721 in view of 6,075,056. The Applicants respectfully traverse.

As delineated in detail in the Applicants' Response to the Final Office Action (see Response, October 10, 2008, pages 6-7), US 2006/0233721 can also trace a priority claim to PCT application IB03/05527, filed October 24, 2003, published as WO 2004/037225. This PCT application claims priority to two earlier filed applications. Most importantly, a discussion of hydrofluoroalkanes as possible propellants in the systems described in this family of applications *does not appear in either priority document*. Indeed, this class of propellants is first mentioned in WO 2004/037225, filed October 24, 2003. Critically, the effective filing date (October 24, 2003) of the disclosure regarding hydrofluoroalkane propellants is AFTER the filing date of the earliest-filed provisional application to which the instant application properly claims priority (October 3, 2003).

Further, US 6,075,056 does not teach hydrofluoroalkane propellants. In other words, combining the teachings of US 2006/0233721 and US 6,075,056 does not resolve the shortcomings of US 2006/0233721 vis-à-vis the requirement for a hydrofluoroalkane propellant in the rejected claims.

Remarks

In the Advisory Action, mailed November 7, 2008, the Examiner has admitted that the cited references do not disclose "hydrofluoroalkane propellants." The Examiner states that these references disclose only "'propellants' in the formulations" and that the term "propellants" has been given its broadest reasonable interpretation.

While the use of hydrofluoroalkanes (HFAs) as an alternative to traditional propellants does not appear in the art cited by the Examiner until after the effective filing date of the present application, the Applicants are willing to acknowledge that HFAs were known propellants at that time. However, in further support of the lack of a *prima facie* case of obviousness, the Applicants respectfully contend that one of ordinary skill in the art at the filing date of the instant application would not have deemed it "obvious to try" veering away from traditional hydrocarbon or chlorofluorocarbon (CFC) propellants in preparing the claimed compositions. Indeed, the specification as filed outlines the potential challenges associated with substituting hydrofluoroalkanes (HFAs) for traditional propellants. The chemical and physical properties of HFAs differ significantly from those of alkanes and CFCs; substitution of HFAs for these propellants would require significant experimentation and reformulation and would not be "obvious to try," therefore.

The challenges associated with replacing CFCs with HFAs in certain pharmaceutical compositions were well known as of the filing date of the instant application. The Montreal Protocol on Substances That Deplete the Ozone Layer was signed in 1987 and banned CFCs from further use; however, exceptions were made until suitable alternatives were discovered for "essential uses" where the public health benefit of using CFCs outweighed the harm to the environment. Many pharmaceutical compositions akin to those claimed still contained CFCs as recently as the time of filing the present application; in other words, no suitable alternative had been found after nearly two decades of research. Accordingly, in light of the implied low expectation of success in using HFA propellants in formulations that historically comprised CFCs, the Applicants respectfully assert that the Examiner has failed to state a *prima facie* case of obviousness for the rejected claims. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Finally, in the recent Advisory Action the Examiner "noted that the same documents were applied as prior art references in the first Office Action and the Applicants had an opportunity to object to the priority at the time of their Response to the said Office Action, and they did not." The Applicants respectfully assert that this objection to Applicants' current arguments has no basis in law or regulation. In other words, the Applicants are not time-barred from introducing the important facts, and legal arguments based on them.

Fees

The Applicants believe that they have provided for the required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any required fee to our Deposit Account, **06-1448** reference **CPX-015.01**.

Conclusion

In view of the above remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,

FOLEY HOAG LLP

/Dana M. Gordon/

Dana M. Gordon, Ph.D.
Attorney for Applicants
Registration No. 44,719

Patent Group
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210

617-832-1000
617-832-7000 (FAX)

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